REMARKS

The Claims

Claims 93 to 103 are currently pending in the application.

Claim Objections

Claims 93 to 103 are objected to for missing the word "protein" being "osteoprotegerin binding" and "of SEQ ID NO:". Claims 93 and 103 have been amended to make this corrections.

Supplemental Information Disclosure Statement

Applicant submits herewith a Supplemental Information Disclosure Statement and SB08 Form and requests that the references set forth therein be considered and made of record in the present application.

Rejections for obviousness-type double patenting

The Examiner has maintained the following rejections against the newly presented claims under the judicially created doctrine of obviousness-type double patenting.

Claims 93 to 103 are rejected as being unpatentable over claims 1 to 25 of U.S. Patent No. 7,364,736 (hereafter the " '736 patent"). It is alleged that

> the issued claims are drawn to a specific antibody species recited by SEQ ID number whereas the instant claims are drawn to a broad genus of antibodies which comprise the same functional properties as the antibodies of the issued claims. [Action at page 4]

Claim 1 of the '736 patent recites an isolated antibody comprising: a heavy chain comprising the amino acid sequence of SEQ ID NO:2;and a light chain comprising the amino acid sequence of SEQ ID NO:4. Claim 2 recites an isolated antibody comprising: a heavy chain

consisting of the amino acid sequence of SEQ ID NO:2; and a light chain consisting of the amino acid sequence of SEQ ID NO:4. Claim 3 recites an isolated antibody comprising: a heavy chain comprising the amino acid sequence of SEQ 13; and a light chain comprising the amino acid sequence of SEQ ID NO:14. Claim 11 recites an isolated antibody comprising: a heavy chain comprising CDR1, CDR2 and CDR3 of SEQ ID NO:13; and a light chain comprising CDR1, CDR2 and CDR3 of SEQ ID NO:14.

The Examiner has argued that the claims of the '736 patent are directed to antibodies having specific sequences where such sequences confer specificity and functional properties of the antibodies that anticipate or render obvious the claims of the present invention. The Examiner cites Examples 1 to 9 and especially paragraph 234 of the '736 specification. Table 4 between paragraphs 234 and 235 indicates that the antibody "alphaOPGL-1" binds to human OPGL with high affinity but does not show specific binding to mouse OPGL. The antibody "αOPGL-1" exhibits the structural features set forth in the claims of the '736 patent and was shown to inhibit the activity of OPGL.

The present claims are directed to an antibody which binds specifically to an epitope on a BB' loop of human OPGbp (or human OPGL). An example of such an antibody is described in the Declaration of John K. Sullivan filed by Applicant with his response of October 14, 2008. The declaration discloses that polyclonal antibodies raised against a BB' loop region peptide (and bind specifically to that region) bind to both human and murine OPGbp (see paragraph 8 and attachment no. 1 of the Declaration). These antibodies were shown to inhibit the activity of OPGbp as shown in attachment no. 2 of the Declaration.

Even though the antibodies of the '736 patent and those of the present application both bind specifically to human OPGbp, they interact differently with OPGbp as evidenced by the ability of "αOPGL-1" to bind human but not murine OPGL while the BB' loop antibody binds to both. Thus, the antibody claims of the '736 patent do not anticipate the present claims. Moreover, it would not have been obvious to modify the antibodies of the '736 patent in order to obtain an antibody having the properties set forth in the present application.

It is requested that rejection over the '736 patent be withdrawn.

Claims 93 to 103 are provisionally rejected as being unpatentable over claims 1-20, 22, 23, 25, 27, 29, 31-34, 36-38, 40, 42-50, 52, 59, 60, 62, 64-67 and 76-87 of copending

Application No. 10/408,901 (hereafter the "'901 application"). It is argued that the specific heavy and light chain sequences recited in the pending claims of the '901 application anticipate the genus of antibodies in the present invention.

The following exhibits related to the prosecution of the '901 application are attached hereto: **EXHIBIT A** is an Amendment and Response mailed March 10, 2009 which includes an amended claim set; **EXHIBIT B** is a Notice of Allowance mailed September 28, 2009 for the claims as set forth in **EXHIBIT A**; and **EXHIBIT C** is the Transmittal of the Issue Fee mailed December 22, 2009.

The Examiner's arguments for the rejection of the claims over the '901 application which are similar to those presented above for the '736 patent. However, the presently claimed antibodies can be distinguished from those in the '901 application. In Example 8 starting on p. 67 and in Figure 24 of the '901 application, all but one of the exemplified antibodies were shown to bind to human OPGL[143-317] but not to murine OPGL[158-316]. By contrast, the Declaration of John K. Sullivan discloses that polyclonal antibodies raised against a BB' loop region peptide (and bind specifically to that region) bind to both human and murine OPGbp. Thus, the sequences claimed in the '901 application do not anticipate the presently claimed antibodies nor would it have been obvious to modify the sequences to produce the presently claimed antibodies.

One antibody in the '901 application, designated 22B3, was observed to bind to both human and murine OPGL. However, 22B3 and several other antibodies in the application were observed to bind specifically to the D-E loop of human OPGL (see p. 70, lines 17-20). This D-E loop region is distinct from the BB' loop region of human OPGL as shown in Figure 1C of Lacey et al. Cell 93, 165-176 (1998) attached hereto as **EXHIBIT D**. This is further evidence that the antibodies of the '901 application interact with OPGL in a manner different from those in the present application.

It is requested that the rejection over the '901 application be withdrawn.

Claims 93 to 103 are provisionally rejected as being unpatentable over claims 10-20, 27-29 and 40-53 of copending Application No. 09/791,153 (hereafter the ""153 application") in view of PCT publication no. WO93/12227 (made of record by Applicant in the Information Disclosure Statement submitted on March 25, 1999). It is argued that the claims of the '153 application

recite antibodies comprising specific Fab sequences that bind human OPGbp, and that these antibodies comprise human Fc domains (citing claims 12 and 13). It is alleged that the claims of the '153 application differ from the instant invention in that they do not teach antibodies of a defined sequence that are human, but WO93/12227 allegedly teaches that human antibodies offer advantages when used as therapeutics, thereby providing motivation to one skilled in the art to convert the antibodies in the '153 application to human antibodies.

The following exhibit related to the prosecution of the '153 application is attached hereto: **EXHIBIT E** is a Response to Notice of a Non-Compliant Amendment and a Preliminary Amendment mailed August 21, 2009.

In the Preliminary amendment, the Applicants have amended the claims of the '153 application as follows: Claims 1-39 and 46-51 have been cancelled, Claims 40-43, 44, and 52-53 have been amended, and new Claims 54-58 have been added. Claim 40 is directed to an antibody or antigen binding domain which recognizes a DE epitope on human OPGbp, wherein the DE epitope comprises the amino acid sequence from residues 212 to 250 of human OPGbp as shown in Figure 29 (SEQ ID NO: 158). Other claims are directed to an antibody or antigen binding domain which recognizes a sequence from residues 230 to 234 on human OPGbp.

The claims currently pending in the '153 application recite a genus of antibodies that bind to a DE epitope on human OPGbp. As indicated above, these antibodies interact with a different region on human OPGbp than the presently claimed antibodies. The presently claimed antibodies are novel and nonobvious over those claimed in the '153 application.

It is requested that the rejection over the '153 application be withdrawn.

Claims 93 to 103 are provisionally rejected as being unpatentable over claims 80 to 91 of copending Application No. 11/981,664 (hereafter the " '664 application"). The '664 application is a continuation application of U.S. Patent No. 7,364,736 and the arguments on the record alleging obviousness-type double patenting over the '664 application are similar to those set forth above for the '736 patent.

The following exhibits related to the prosecution of the '664 application are attached hereto: **EXHIBIT F** is a Restriction Requirement mailed September 2, 2009; **EXHIBIT G** is a

Response to an Office Action mailed December 2, 2009; and **EXHIBIT H** is an Office Action mailed February 5, 2010.

The Examiner has indicated that Claims 30 to 91 in the '684 application are subject to a restriction to one invention. Applicants have elected to prosecute Group I corresponding to Claims 30 to 53. This group corresponds to claims "drawn to nucleic acids, vectors, host cells, and methods of making polypeptides from said host cells, classified in class 536, subclass 23.1." In the subsequent Office Action, Applicants' election of Group I was acknowledged.

Group I is considered patentably distinct from Group 4, which corresponds to claims 80 to 91 directed to antibodies. Accordingly, the rejection in view of claims 80 to 91 of the '664 application may be withdrawn.

CONCLUSION

Claims 93 to 103 are believed to be in condition for allowance and it is requested that the application be passed to issuance. Should any outstanding issues remain, the Examiner is invited to call the undersigned at (805) 447-2425 to arrange for an interview.

Respectfully submitted,

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